(1) Publication rumber.

0 373 753

EUROPEAN PATENT APPLICATION

- (2) Application number: 89310314.3
- 15/00, B65D 83/14
- @ Date of filing: 09.10.89

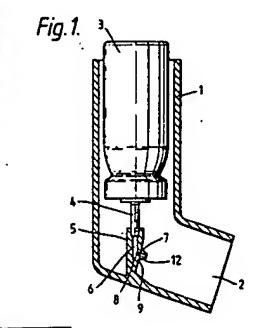
The title of the invention has been amended (Guidelines for Examination in the EPO, A-III." 7.31

- Priority: 22.10.88 GB 8824804
- Date of publication of application: 20.06.90 Bulletin 90/25
- Designated Contracting States: AT BE CHOE ES FR GB GR IT LI LU NL SE
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Aerosol inhalation device.

An aerosol inhalation device (1) suitable for use in association with a pressurised medicament cortainer (3) having a velve stem (4) has a spray head (5) adapted to receive the valve stem (4). The spray head (5) has an outlet ortice which is provided with a spout (12). The device is especially useful in the administration of hygroscopic medicaments, for example sodium cromoglycate or nedocromil sodium.





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having a mouthpiece 2. The housing 1 receives a container 3 of pressurised medicament, the container being provided at one and with a metaring raive including a valve stem 4. The seated in a spray head 5. The spray head 5 includes an internal cavity 6 provided with an outlet orifice 7. The internal cavity 6 has a lower portion 8 which extends below the outlet orifice 7.

As can be seen more clearly from Figure 2, the outlet orifice 7 passes through a spout 12 which 70 has a generally frusto-conical shape with a concave outer wall. The spout 12 rises out of a flat front surface 9 of the spray head 5, the fixt surface being at an angle such that the spout 12 is directed towards the moutholece 2:

To use the device, a patient inhales at the mouthplece 2 while simultaneously urging the medicament container 3 towards the spray head 5. The relative motion of the container 3 and the valve stem 4 causes the metering valve to open and medicament to be discharged into the valve stem 4. The medicament then passes through the internal cavity 8 of the spay head, and finally through the outlet orifice 7 after which it is inhaled by the patient through the mouthpiece 2.

Ctairns

outlet orlice.

- 1. An aerosol inhalation device suitable for use in association with a pressurized medicament container having a valve stem, the device comprising a spray heed adapted to receive the valve stem and . having an outlet orifice, characterised in that the outlet ortice is provided with a spout.
- 2. An aerosol inhabition device according to claim 1, wherein the spout is generally frustoconical in shape.
- 3. An aerosol inhetation device according to claim 2, wherein the curved outer surface of the 40 spout is concave. 4. An aerosol inhabition device according to
- is tess than tûrnin in length. 5. An aerosol inhalation device according to 45 eny one of the preceding claims, wherein the spout

any one of the preceding claims, wherein the spout

- is less than 5mm in length. 8. An serosol inhalation device according to any one of the preceding claims, wherein the spray head includes an internal cavity which is open at 60 one and to receive the valve stem and closed at the other end, the cavity extending beyond the
- 7. An aerosol inhalation device according to any one of the preceding claims, wherein the oudet critice is of uniform cross section throughout its
 - 8. An aerosol inhatation device comprising a

pressurised medicament container having a valve stam, a spray head adapted to receive the valve stam and having an outlet orifice, characterised in critice is provided with a spout.

9. An aerosol inhalation device according to ctain 8, wherein the medicament is hygroscopic.

10. An aerosol inhalation device according to ciaim 9, wherein the medicament is sodium cromoglycate or nedocromit sodium.

IMPROVEMENTS TO AEROSOL DEVICES

This invention relates to improvements in serosol devices, more perticularly to those for the dispensing of medicaments for inhabition.

The use of esrosal inhalation devices for the administration by Inhalation of medicaments in the form of powder serosols is well known. Such devices generally comprise a housing which receives a canister of pressurised medicament. The canister is provided with a dispensing metering valve including a metoring chamber and a hollow valve stern which locates in a spray head within the

Medicament is discharged by moving the canistor relative to the valve stem. This changes the dispansing metaring valve from an inoperative state in which the metering chamber is isolated from the atmosphere to an operative state in which the metaring chamber communicates with the atmosphere via the valve stem and an outlet orifice provided in the spray head. Thus, in the operative state medicament can pass from the chamber through the valve stem, the spray head and the outlet orifice into the housing from where it can be inhaled by a user via a mouthpiece formed in the housing.

A problem which can occur with devices of this type is blockage of the outlet orifice. Also, medicament may build up around the outlet orlines and form a plug which may subsequently be disindged and inheled by the user.

We have now surprisingly found that these 30 problems can be eliminated or substantially mitigated by providing the outlet orifice with a spout.

Thus, according to the present invention there is provided an aerosot inhalation device suitable for use in association with a pressurised medicament — as container having a valve stam, the device comprising a spray head adapted to receive the valve stam and having an outlet orifice, characterised in that the outlet orlice is provided with a spout.

We prefer the spout to be generally trustoconical in shape. We particularly prefer the spout to be trusto-conical and the curved outer surface of such a spoul to be concave.

We prefer the spout to be less than 10mm and more preferably tess then 5mm in length, for example 2mm. The ratio of the length of the outlet orifice to the length of the spout is preferably less than 2:1.

The spray head includes an internal cavity which is open at one end to receive the valve stam. and closed at the other end. The cavity may extend beyond the outlet orifice.

We prefer the outlet crifice to be of uniform cross section throughout its length. We further prefar the outlet orifice to be circular in cross section.

The device of the present invention is used in conjunction with a carrister of pressurfeed medicament. Thus, the present invention further provides an aerosol inhelation device comprising a pressurised medicament container having a valve stam, a spray head adapted to receive the valve storn and having an outlet critice, characterised in that the outlet orifice is provided with a spout.

We have found that the problem of blockage is particularly marked when the medicament is hygrescopic. Thus, the spouted inhabition devices of the present invention are particularly useful for administering hygroscopic medicaments.

By "hygroscopic medicament" we mean a medicament which takes up significant amounts of water when in a moist atmosphere, for example one which at 90% relative humidity (being approximately a lower value for the relative humidity found in human breath) takes up more than 8% of its own weight of water. Examples of such medicaments include sodium cromoglycate and nedocromii so-

The serosol inhalation devices of the invention have the advantages that they do not become blocked or block less frequently, so that a canister of medicament can be exhausted without the danper of the device being discarded prematurely because the netlect mistekenty believes that the carister is empty or because it cannot readily be unblocked; there is a greatly reduced risk of plugs of medicament forming in the devices which are subsequently inhaled by the patient - such inhaletion may lead to over-dosing or a coughing spasm which is expecially dangerous for patients who have breething difficulties and who are most likely to be using serosol inhelation devices; the devices are more hygienic because there are fewer or no medicament accretion auritaces which bactaria may coloriza; and they need to be cleaned tess fraquently - cleaning being a difficult task for pedent who have unsteady hands.

A preferred embodiment of a device according to the invention will now be described, by way of example, with reference to the accompanying drawings, in which:

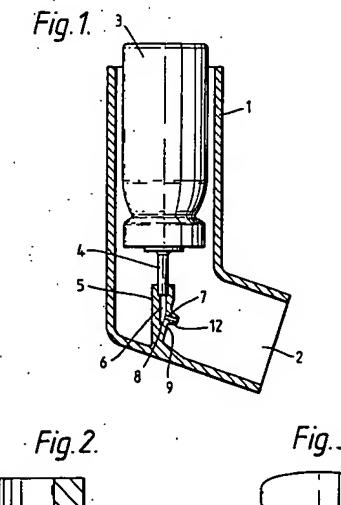
Figure 1 is a side view in partial section of an serosol inhelation device according to the invention fitted with a pressurized medicament container;

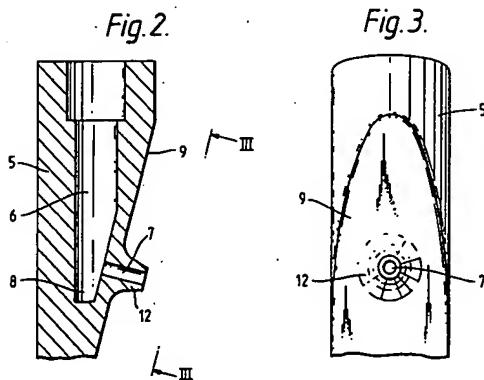
Figure 2 is an expanded view of the sprayhead of the device shown in Figure 1 (also here in cross-section) and:

Figure 3 is a view of the spray-head shown in Figure 2 along the line III-IIL Referring first to Figure 1, an aerosol inheiztion

device comprises a generally cylindrical housing 1

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Application Number

EP 89 31 0314

DOCUMENTS CONSIDERED TO BE RELEVANT				
Category	Citation of decrement with in of relevant per	dication, where appropriate,	Referent to claim	CLASSIFICATION OF THE APPLICATION (SEL CL.5)
X	FR-A-2 603 809 (GL) * Page 3, 11ne 24 - figures 1-3 *	NO CROUP)	1-8	A 61 M 15/00 B 65 D 83/14
Y	ilgures 1-3		9,10	
Y	EP-A-0 089 070 (FI * Page 1, lines 2-4 page 6, line 7 *		9,10	
X	EP-A-0 132 352 (GL * Page 3, lines 1-2	NCO GROUP) 1; figures 1,6,8 *	1	
x	US-A-3 913 842 (SII * Column 1, lines 1: 3-14; column 3, line		1-3,6-8	
				TECHNICAL FIELDS SEARCHED (SA. CLS)
				A 61 M B 65 D
	-			
The present search report has been drawn top for all claims Find of search Sub-of search of the result				Busher
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CATEGORY OF CITED DOCUMENTS X : puricularly relevant if tohan stime Y : puricularly relevant if commissed with stochan document of the cases conservy A : technological bedrapount		L i decement d	T: theory or principle underlying the invention E: mather parent december, but published on, or after the filling date D: december clock in the application L: december clock for other respect	
O : num-retion disclosure P : Interpolitate decisions decisions				t), consequent